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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,080	08/30/2001	Carlo Effenhauser	RDID01056US	7687

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Roche Diagnostics Corporation
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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,080	EFFENHAUSER ET AL	
	Examiner	Art Unit	
	Brian Szmaj	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-14-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 15 is objected to because of the following informalities: In line 2, "at least one analytes" should read as "at least one analyte". In line 3, the word "it" should be replaced since the word is considered to be indefinite. Appropriate correction is required.
2. Claim 16 is objected to because of the following informalities: In line 2, the word "it" should be replaced, since the word is considered to be indefinite. Appropriate correction is required.
3. Claim 20 is objected to because of the following informalities: In line 1, "System as claimed" should read as "The system as claimed". Appropriate correction is required.
4. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

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5. Claims 14-17 and 20-23 are objected to because of the following informalities:

The claims refer to cancelled Claim 1. For purposes of examination, the Examiner has assumed that the dependency of the claims refer to Claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mauze et al (6,375,627 B1) in view of Garcia et al (4,637,403).

Mauze et al disclose a physiological fluid extraction means with rapid analysis and further disclose a drive unit; a disposable lancing unit which has a holding area that is removably positioned in the holder; an elongate capillary structure, wherein a proximal end of the capillary structure comprises at least one capillary channel for transporting a body fluid connected to the holding area; a distal end of the capillary structure suitable for piercing the skin, wherein the capillary structure is located outside the skin in a first position and inserted into the skin in a second position; the capillary channel is open to the outside in an area which comprises at least part of the longitudinal extension of the capillary structure; the entire length of the capillary structure is open to the outside; the holding area has a detection zone for detecting at least one analyte, the detection zone

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being arranged to use capillary action to take up the body fluid; the capillary structure and the holding area are integrally connected together; the capillary structure that is open to the outside has a channel shape; the channel shape is a V-shaped cross-section; the length of the capillary structure is in the range of 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm; and the holding area and the capillary structure are made of silicon. See Column 2, lines 27-29; Column 3, lines 22-39 and 50-55; Column 4, lines 15-30; Column 5, lines 55-67; Column 6, lines 1-20, 26-31, 54-56 and 67; Column 7, lines 1-7; and Figures 1, 6 and 7.

Even though Mauze et al disclose a drive unit, the specifics of the drive unit are not explained. For instance, Mauze et al fail to disclose the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position; and the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval and subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin.

Garcia et al disclose the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position; and the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval and subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin. See Column 9, lines 41-66; and Column 12, lines 15-21.

Since both Mauze et al and Garcia et al disclose drive units, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Mauze et al to include the specifics of the drive unit of Garcia et al, since it would provide a means of moving the lancing unit to acquire a fluid sample.

Response to Arguments

8. Applicant's arguments filed December 14, 2004 have been fully considered but they are not persuasive. The Examiner respectfully disagrees with the argument that the device of Mauze et al fails to disclose an open channel along the length of the device. Mauze et al disclose a sampling means with an open channel, as shown in Figure 1, where there are solid lines denoting the channel (20). If the channel were not open to the outside, the lines would be dashed lines and not solid lines. Furthermore, due to the disclosure of the etching process to etch the silicon substrate to obtain a channel, one of ordinary skill in the art would be able to recognize that an open channel is created in the silicon substrate. Assuming, for argument's sake, that Figure 1 does not disclose an open channel, as stated in the Applicant's arguments, Figure 1 still shows the distal end of the lancing device (18, 22) as a pointed end without anything covering the distal end. Therefore, the distal end would constitute an open channel, per the requirements of "at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-

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4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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